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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,928	03/23/2005	Marc Hubert Mercken	PRD-0032-USPCT1	4646

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EXAMINER

WANG, CHANG YU

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/528,928

Applicant(s)

MERCKEN ET AL.

Examiner

Chang-Yu Wang

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-11 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**  
**RESPONSE TO AMENDMENT**

***Status of Application/Amendments/claims***

Applicant's amendment filed July 17, 2006 is acknowledged. Claim 12 is cancelled. Claims 1-11 and 13-16 are pending in this application and under examination in light of a monoclonal antibody that specifically recognizes A $\beta$ 11-x peptides and a diagnostic/immunoassay kit comprising the antibody. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

***Claim Rejections/Objections Withdrawn***

The rejection of claims 6-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in response to Applicant's amendment of including the information of biological deposited materials and the statement that the Belgian Coordinated Collection of Microorganisms is an International Depositary Authority established under the Budapest Treaty in the specification.

The rejection of claim 10 under 35 U.S.C. 102 (b) as being anticipated by Walker et al (J. Neuropathol. Exp. Neurol. 1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) and Naslund et al (as in IDS submitted on Mar 23, 2005) is withdrawn because the claim recites the limitation of the antibody being expressed by the hybridoma cells recited in claim 7.

***Claim Rejections/Objections Maintained***

***Claim Rejections - 35 USC § 102***

The rejection of Claims 1-5, 8, 9, 11 and 13-16 under 35 U.S.C. 102 (b) as being anticipated by Walker et al (J. Neuropathol. Exp. Neurol. 1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) and Naslund et al (as in IDS submitted on Mar 23, 2005) is maintained. The rejection is maintained for the reasons set forth in the previous office action and restated herein.

Applicant argues that the antibody 10D5 disclosed in the Walker et al. reference is for the N-terminal of A $\beta$  and generated from the immunogen consisting of the first 1-16 aa of A $\beta$ . The instant antibodies are specific for the truncated form of A $\beta$  that is cleaved at the position of 11 of A $\beta$ . In addition, the instant antibodies do not cross react with other APP fragment and are useful for diagnosis of pathogenesis of Alzheimer's disease. Applicant argues that the antibody disclosed by Walker et al. can only detect total Ab and does not distinguish the truncated forms from the full length of A $\beta$ . Applicant further argues that the monoclonal antibodies disclosed in the references of Pirttila et al. and WO0162801 are for A $\beta$ 13-28 and do not detect A $\beta$ 11-x. Applicant argues that Naslund et al. reference detects total A $\beta$  and the identification of A $\beta$ 11-40 is analyzed by MS-analysis, and the antibody disclosed in the reference does not have the specificity of the claimed antibodies.

Applicant's arguments have been fully considered but they are not found persuasive. It is noted that Applicant claims a composition in terms of a function, property or characteristics is the same as the prior art products. "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3]. In response to Applicant's arguments that none of art antibodies can differentiate the full-length and truncated forms of A $\beta$ , the Examiner has made the prima facie case that the art antibodies raised against A $\beta$ 1-16 and A $\beta$ 13-28 immunogens can bind to the epitopes of A $\beta$ 11-x as evidenced by Huse et al (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284). Huse et al. teach that BNT77, a monoclonal antibody against amino acids 11-16 of A $\beta$ , can recognize both full-length and N-terminal truncated species of A $\beta$ . Since an antibody against 11-16 can recognize an N-terminal truncation, the examiner asserts that an antibody against 1-16 could also recognize the N-terminal truncated A $\beta$  including A $\beta$ 11-x. In addition, Huse et al. teaches that 4G8, a monoclonal antibody against amino acids of 17-24 of A $\beta$ , can detect A $\beta$ 1-40, A $\beta$ 11-40,

A $\beta$ 1-34 and A $\beta$ 11-34 species of A $\beta$ . Thus, an antibody against 13-28 would have the same properties. Applicant has provided no showing that the antibodies in the art have characteristics different from those specified by Applicant and do not in fact bind to the same epitopes.

The antibody, 10D5 against A $\beta$ 1-16 as disclosed by Walker et al., the antibodies, 6E10 against A $\beta$ 1-16 and 4G8 against 13-28, as disclosed by Pirttila and the antibody, m266 against A $\beta$ 13-28, as disclosed by WO0162801 do bind to A $\beta$ 11-x as shown in Huse et al. and WO0162801. In addition, the binding property of the art antibodies to A $\beta$ 11-x is an inherent feature of these antibodies. The Examiner would like to point out that "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed. Cir. 1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on

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sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.”); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) (“Because sufficient aeration’ was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.”)>; *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound “inherently” anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound “inherently results in at least trace amounts of” the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<.” See MPEP § 2112 (II). Thus, the rejection of claims 1-5, 8, 9, 11 and 13-16 under 35 U.S.C. 102 (b) as being anticipated by Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) and Naslund et al (as in IDS submitted on Mar 23, 2005) is maintained.

### ***Specification***

The disclosure is objected to because of the following informalities: The descriptions of A $\beta$  peptides (A $\beta$ \_11(5AA/7AA, SEQ ID NOs:1-4) on p. 4, figure 1A, lines 32-35 are not consistent with the descriptions on p. 3, lines 32-35, p. 17, lines 7-10 and p. 19, lines 9-11 (A $\beta$ \_11(6AA/8AA, SEQ ID NOs:1-4). In addition, the sequences listed on p.19, lines 9-11 need a sequence identifier. Appropriate correction is required.

***New Grounds of Rejection***

***Claim Objections***

Claims 6 and 7 are objected to because of the following informalities: the typographical error of accession numbers. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14,16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of A $\beta$ 11-40 in the CSF and brain section of Alzheimer's disease by using antibodies raised against A $\beta$  peptides consisting of 6-8 amino acids of A $\beta$ \_11 (6AA) or A $\beta$ \_(8AA) (SEQ ID NOs: 1-4), does not reasonably



provide enablement for using the antibodies that specifically bind to A $\beta$ 11-x peptides to diagnose all amyloid-related diseases as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

"There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'. These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)". See MPEP § 2164.01.

Claims are directed to a diagnostic composition or an immunoassay kit comprising antibodies raised against A $\beta$  peptides of SEQ ID NOs: 1-4. Applicant discloses that antibodies generated from A $\beta$ \_11(6AA or 8AA, SEQ ID NOs:1-4) can

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detect A $\beta$ 11-40 in CSF and brain sections of AD patients. Applicant further describes that antibodies raised against SEQ ID NOs 1-4 do not cross react with synthetic A $\beta$ 1-40 in a Western blot. However, Applicant also shows that these antibodies can be used to detect different forms of A $\beta$  including A $\beta$ 1-40/1-42/11-40 in different species including human using an ELISA method (see p. 23, line 25). Applicant describes that A $\beta$ 11-40 is a major form of amyloid peptides found in AD. However, different A $\beta$  N-terminal variants are also found in human amyloid plaques including A $\beta$ 1-x, A $\beta$ 3-x, A $\beta$ 11-x and A $\beta$ 17-x and so are A $\beta$ x-42 and A $\beta$ x-40 (see p. 241, abstract, Tekirian J. *Alzheimers Dis.* 2001. 3: 241-248). In addition, it is still not clear whether the N-terminal truncated forms of A $\beta$  especially pyroglutamylated A $\beta$ py11-42 is the cause of AD in AD patients with presenilin-1 mutation because detectable A $\beta$ 1-42 is more abundant than detectable A $\beta$ py11-42 in plaques, which argues against the pathogenic role of A $\beta$ 11-42 (see p. 343. Larner. *Neurobiol. Aging.* 2001. 22: 343) and whether detecting A $\beta$ 11-42 can diagnosis the disease or even other amyloid-related disease. Thus, it is unpredictable whether detecting A $\beta$ 11-40 can detect/diagnose all amyloid-related diseases since multiple forms of A $\beta$  variants are present in amyloid deposits and A $\beta$ 1-42 is more abundant than A $\beta$ 11-40; and A $\beta$ 11-140 is also detectable in control as shown in the specification (see p. 23, line 25). Although Applicant is enabled for detecting the A $\beta$ 11-40 in CSF and brain sections of AD patients, it is unpredictable whether Applicant is able to diagnose other forms of Alzheimer's disease that are caused by other forms of A $\beta$  since the claimed antibodies are raised against A $\beta$ \_11 (6AA or 8AA) peptides that

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only consist of 5-7 amino acids of A $\beta$  and can not recognize A $\beta$  variants that do not have these 5-7 amino acids of A $\beta$ . In addition, it is unpredictable whether the claimed antibodies can be used to diagnose other amyloid-related disease because whether A $\beta$ 11-40 can be found in other amyloid-related diseases other than Alzheimer's disease is unknown and several types of N-terminal fragments of A $\beta$  can be found amyloid deposits and cause formation of amyloid deposits. Therefore, in view of the necessity of experimentation, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention as it pertains to a diagnostic composition or an immunoassay kit comprising antibodies raised against A $\beta$  peptides of SEQ ID NOs: 1-4.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 provide for the use of a monoclonal antibody that specifically recognizes A $\beta$ 11-x peptides for diagnosis of  $\beta$ -amyloid-related disease, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites "carrier means" in the claim. Applicant describes several possibilities of carrier on p. 9, line 21. However, the description is not definite because Applicant fails to define/describe what is encompassed in the definition of "carrier means". The disclosure fails to set for the metes and bounds of what is encompassed within the definition of such carrier means; thus the claim is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 8, 14-16 are rejected under 35 U.S.C. 102 (b) as being anticipated by Solomon et al. (Proc. Natl. Acad. Sci. USA. 1996. 93: 452-455).

Solomon et al. teach two monoclonal antibodies AMY-33 and 6F/3D raised against amino acids 1-28 and 8-17 of A $\beta$  respectively. Although the reference is silent in view of A $\beta$ 11-x, the antibodies raised against aa 1-28 and 8-17 would inherently recognize A $\beta$ 11-x because the amino acid sequence of the immunogens (5-7 amino acids of A $\beta$ 11-x) for the instant antibodies are encompassed in the sequences of amino acids 1-28 and 8-17 of A $\beta$ . Thus, the

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epitopes generated from the instant immunogens are overlapped by the sequences of art immunogens. In addition, the intended use recited in claims 14-16 are not given patentable weight. Thus, the reference fairly anticipates the limitation recited in the claims. Accordingly, claims 1-2, 5, 8, 14-16 are anticipated by Solomon et al.

Claims 1-2, 5, 8, 14-16 are rejected under 35 U.S.C. 102 (a) as being anticipated by Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284).

Huse et al. teach that the level of A $\beta$ 11-40/42 is significantly increased in post-mortem AD patients' brains. Huse et al. teaches BNT77, a monoclonal antibody raised against amino acids 11-16 of A $\beta$ , which meets the limitation of antibodies recited in claims 1 and 2 (see p. 16279, 1<sup>st</sup> col., 4<sup>th</sup> paragraph). Huse et al. also teach a monoclonal antibody 4G8 that can detect A $\beta$ 1-40, A $\beta$ 11-40, A $\beta$ 1-34 and A $\beta$ 11-34, which also meets the limitation recited in claims 1 and 2. Huse et al. further teaches that a method of detecting Ab11-40/11-42 in Alzheimer's brains (see p. 16279, 1<sup>st</sup> col. 5<sup>th</sup> paragraph; p.16282, 2<sup>nd</sup> col. 2<sup>nd</sup> paragraph), which meets the limitation recited in claims 8 and 14. In addition, the intended use recited in claims 14-16 are not given patentable weight. Therefore, claims 1-2, 5, 8, 14-16 are anticipated by Huse et al..

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8, 9, 11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol. 1994 Jul. 53: 377-383 as cited in the previous office action) and WO0162801 (as in IDS submitted on Mar 23, 2005 and cited in the previous office action).

Huse et al. teach as set forth above but fail to teach the claimed antibodies are detectably labeled.

Walker et al. teach anti-A $\beta$  monoclonal antibody 10D5 generated from an immunogen of A $\beta$ 1-16 peptides binds to A $\beta$  deposits in the brain (see p. 377, Abstract.). Walker et al. further teach detecting Amyloid deposit in the subject in vivo using 10D5 A $\beta$  monoclonal antibody (see p. p382, the last second paragraph). Although the reference is silent in view of Ab11-x, the antibody

against 1-16 is able to bind to Ab11-x. Thus, the reference meets the limitation recited in claims 1, 2, 5, 8 and 13-16. But, Walker et al. fails to teach to detect Ab11-x in a body fluid sample.

WO0162801 teaches an anti-A $\beta$  monoclonal antibody 266, which recognizes A $\beta$ 13-28 (see p.5, first paragraph). WO0162801 also teaches a method of detection of A $\beta$  in the brain tissue and CSF of Alzheimer's disease patients using labeled antibodies by electrophoresis or ELISA (see p.26, examples 1-2; p. 30, example 6). Although the reference is silent in view of A $\beta$ 11-x, the antibody against 1-16 is able to bind to A $\beta$ 11-x. Thus, the reference meets the limitation recited in the claims 1-5, 8, 9, 11 and 13-16.

It would have been obvious for one of ordinary skill in the art at the time of the instant invention was made to use an antibody raised against A $\beta$ 11-16 or use antibody that can recognize A $\beta$ 11-x to detect A $\beta$ 11-x in Alzheimer's disease because the level of A $\beta$ 11-40/42 has been shown increased in AD patients. The person of ordinary skill in the art would have been motivated to do so because the antibody against A $\beta$ 11-16 has been shown to be able to detect A $\beta$ 11-40/42 in AD brains. Thus, One of ordinary skill in the art would have expected success in generating an antibody against the amino acids 5-7 of A $\beta$ 11-x and using the antibody to detect A $\beta$ 11-40/42 in AD patients.

***Conclusion***

***Allowable Subject Matter***

Claim 6 is objected to as being dependent upon a rejected base claim; i.e. claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 7 is allowed.

Claims 1-5, 8-11 and 13-16 are rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW

August 23, 2006

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER